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**NEW UTILITY PATENT APPLICATION
TRANSMITTAL****(Large Entity)***(Only for new nonprovisional applications under 37 C.F.R. 1.53(b))*

Docket No. S63.2-9178

Total Pages in this Submission

(including checks and postcard)

36

Box Patent Application
 Commissioner for Patents
 Washington, D.C. 20231

Transmitted herewith for filing under 35 U.S.C. 111(a) and 37 C.F.R. 1.53(b) is a new utility patent application for an invention entitled: MOISTURE CURABLE BALLOON MATERIALS

and invented by: John Jianhua Chen

If a CONTINUATION APPLICATION, check appropriate box and supply the requisite information:

☐ Continuation ☐ Divisional ☐ Continuation-in-part (CIP) of prior application No.: _____

Enclosed (in addition to the 4 pages of this transmittal) are:

4 pages

Application Elements**1. ☒ Filing fee as calculated below:**

a. ☐ filing fee is NOT ENCLOSED - fee will be paid at the time of responding to the Notice of Missing Parts -- DO NOT CHARGE DEPOSIT ACCOUNT

b. ☒ a check in the amount of \$890.00 to cover the filing fee is enclosed.

1 page

c. ☐ charge to Deposit Account as authorized at Item 2(a) on next page.

FEE CALCULATION AND CLAIMS

For	No. Filed	No. Allowed	No. Extra	Rate	Fee
Total Claims	30	- 20 =	10	x \$18.00	\$180.00
Indep. Claims	3	- 3 =	0	x \$80.00	\$ 0.00
BASIC FEE					\$710.00
TOTAL FILING FEE					\$890.00

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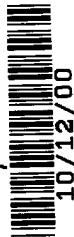
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JC921 U.S. PTO
09/689139



2. The Commissioner is hereby authorized to charge and credit Deposit Account No. 22-0350 as described below. A duplicate copy of this sheet is enclosed.
- ☐ Charge the amount of \$____ as filing fee.
 - ☒ Credit any overpayment.
 - ☒ Charge any additional filing fees required under 37 C.F.R. 1.16 and 1.17.
 - ☐ Charge the issue fee set in 37 C.F.R. 1.18 at the mailing of the Notice of Allowance, pursuant to 37 C.F.R. 1.311(b).
3. ☒ Specification having 19 pages and including the following: 19 pages
- ☒ Application Cover Sheet - 1 page
 - ☒ Descriptive Title of the Invention -
 - ☐ Cross References to Related Applications *(if applicable)*
 - ☐ Statement Regarding Federally-sponsored Research/Development *(if applicable)*
 - ☐ Reference to Microfiche Appendix *(if applicable)*
 - ☒ Background of the Invention
 - ☒ Brief Summary of the Invention
 - ☒ Brief Description of the Drawings *(if applicable)*
 - ☒ Detailed Description
 - ☒ Claim(s) as Classified Below - 6 pages
 - ☒ Abstract of the Disclosure - 1 page
4. ☒ Drawing(s) *(when necessary as prescribed by 35 U.S.C. 113)* 1 sheet 1 page
5. ☒ Oath or Declaration - 3 pages
- ☒ Newly executed *(original or copy)* ☐ Unexecuted
 - ☐ Copy from a prior application (37 C.F.R. 1.63(d)) *(for continuation/divisional application only)*
6. ☒ Separate Power of Attorney 1 page
- ☐ 37 C.F.R. 3.73(B) Statement *(when there is an assignee and power of attorney is from assignee)*. It is hereby certified that the undersigned has authority to make this certification and has reviewed all the documents in the chain of title of the patent application identified herein and, to the best of undersigned's knowledge and belief, title is in the assignee identified in the accompanying Power of Attorney.

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09/689139



☐ Power of Attorney filed in parent application.

7. ☐ Incorporation by Reference *(usable if Box 5b is checked)*

The entire disclosure of the prior application, from which a copy of the oath or declaration is supplied under Box 5b, is considered as being part of the disclosure of the accompanying application and is hereby incorporated by reference therein.

8. ☐ Computer Program in Microfiche *(Appendix)* _____ pages

9. ☐ Nucleotide and/or Amino Acid Sequence Submission _____ pages
(if applicable, all must be included)

a. ☐ Paper Copy

b. ☐ Computer Readable Copy *(identical to computer copy)*

c. ☐ Statement Verifying Identical Paper and Computer Readable Copy

Accompanying Application Parts

10. ☒ Assignment Papers: 3 pages

a. ☒ Assignment Recordation Cover Sheet (Form PTO 1595)

b. ☒ Assignment

c. ☒ A check in the amount of \$40.00 to cover the Recordal Fee

d. ☐ Previously recorded on ***, Reel **, Frames **

11. ☐ English Translation Document *(if applicable)* _____ pages

12. ☐ Information Disclosure Statement: _____ pages

a. ☐ PTO Form 1449 b. ☐ Copies of IDS Citations

13. ☐ Preliminary Amendment _____ pages

14. ☒ Acknowledgment Postcard 1 page

15. ☒ Form of Mailing - Express Mail *(Specify Label No.):* EL668460647US

16. ☐ Certified Copy of Priority Document(s) *(if foreign priority is claimed)* _____ pages

NEW UTILITY PATENT APPLICATION TRANSMITTAL (Large Entity) <i>(Only for new nonprovisional applications under 37 C.F.R. 1.53(b))</i>	Docket No. S63.2-9178
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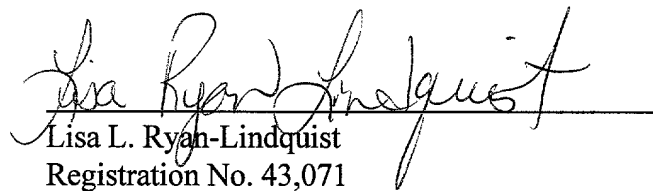
17. ☒ Additional Enclosures *(please identify below)*: 3 pages
- ☒ Constructive Petition for Extension of Time and Fee Authorization Pursuant to 37 C.F.R. §1.136(a)(3) - 1 page
 - ☒ Correspondence Address form - 1 page
 - ☒ Limited Authorization to Act on Behalf of Assignee Regarding Certain Patent Matters
Effective Through: December 31, 2000 - 1 page

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: October 12, 2000

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DOCKET NO. S63.2-9178

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
APPLICATION FOR UNITED STATES LETTERS PATENT**

INVENTOR(S): John Jianhua Chen

TITLE: MOISTURE CURABLE BALLOON MATERIALS

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MOISTURE CURABLE BALLOON MATERIALS

FIELD OF THE INVENTION

The present invention relates to the preparation of thin films useful in
5 medical devices, and in particular in the manufacture of medical dilatation balloons,
formed from a durable polymeric composition crosslinked upon exposure to moisture
through --Si--O--Si-- linkages. More particularly, the balloons are formed from the
reaction product of at least one organofunctional hydrolyzable silane and at least one
polymer, the reaction product of which is crosslinked by exposure to moisture. The
10 crosslinked structure increases the toughness, abrasion resistance, durability and
dimension stability of the material during both manufacturing procedures and during use.

BACKGROUND OF THE INVENTION

Balloon catheters are used in procedures relating to the treatment of
15 stenoses or blockages in body vessels, an example of which is an arterial stenosis which
is commonly treated by angioplasty procedures which involve the insertion of balloon
catheters into the affected blood vessel of the patient.

The balloon may function to widen a vessel into which the catheter is
inserted, to force open a blocked vessel to open the blocked or collapsed blood vessel, or
20 to prop open the a collapsed vessel. The requirements for strength and size of the
balloons vary widely depending on the balloon's intended use and the vessel size into
which the catheter is inserted. Perhaps the most demanding applications for such
balloons are in balloon angioplasty in which catheters are inserted for long distances into
extremely small vessels and used to open stenoses of blood vessels by balloon inflation.

25 Balloon angioplasty requires extremely thin walled, high strength (i.e.
high tensile), relatively inelastic balloons of predictable inflation properties.

Thin walls are necessary because the balloon's wall and waist thicknesses
limit the minimum diameter of the distal end of the catheter and therefore determine the
limits on vessel size treatable by the method and the ease of passage of the catheter
30 through the vascular system. High strength is necessary because the balloon is used to
push open a stenosis and so the thin wall must not burst under the high internal pressures

necessary to accomplish this task. The balloon must have some elasticity so that the inflated diameter can be controlled, so as to allow the surgeon to vary the balloon's diameter as required to treat individual lesions, but that elasticity must be relatively low so that the diameter is easily controllable. Small variations in pressure must not cause

5 wide variation in diameter.

To achieve the high strength, thin walled properties, catheter balloons are often made of biaxially oriented polyethylene terephthalate (PET) or a polyamide material such as nylon 12. These materials, however, tend to be less elastic, and have less resilience.

10 Balloon catheters may also be made of more elastic materials such as polyolefins or polyolefin copolymers, but typically, in order to achieve the high tensile strength, the balloon walls must be made thicker.

One difficulty experienced in the case of the high strength, thin walled materials, such as PET is that they can be punctured through abrasion or the like, even
15 though they have a high tensile strength. Pin holes and ruptures can occur when such catheter balloons are used in contact with rough surfaces. Also, tiny flaws in the mold of such balloons can create weak spots, since the balloons are so thin-walled.

It is, however, typically impractical to increase the wall thickness of these biaxially oriented, non-resilient materials because they become too stiff, with high
20 flexural moduli, with the result that such balloons do not collapse properly on deflation to facilitate easy withdrawal from the vascular system of a patient.

The balloons can be coated with a more abrasion resistant material, but coatings add a step during the manufacturing process, typically decrease flexibility, and also typically increase the wall thickness.

25 There remains a need for a balloon catheter which is thin walled, durable, abrasion and tear resistant thereby improving the resistance to pinhole formation, and is relatively flexible, yet inelastic to allow the balloons to expand outwardly to a predetermined diameter, and then cease further expansion at normal pressures, to avoid damage to the artery wall by overexpansion.

30

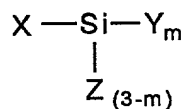
SUMMARY OF THE INVENTION

The present invention relates to a medical device such as a balloon catheter comprising a dilatation balloon wherein said balloon comprises a moisture cured polymeric material which is crosslinked through --Si-O-Si-- linkages.

5 The present invention further relates to a catheter balloon comprising the reaction product of at least one polymer and at least one organofunctional hydrolyzable silane having an organofunctional group capable of readily reacting with the moieties on the polymer backbone. The silane is grafted onto the polymer backbone and the hydrolyzable groups of the silane are activated by moisture, crosslinking the structure
10 through --Si-O-Si-- linkages.

The present invention further relates to a medical device comprising a dilatation balloon formed from a crosslinked polymeric material, the crosslinked polymeric material comprises the reaction product of at least one polymer and at least one hydrolyzable silane having the following general structure:

15



where X is a monovalent non-hydrolyzable organic moiety comprising at least one
20 functional group W which is reactive with said polymer with the proviso that an Si-C bond is present between Si and W, Y is a hydrolyzable group, Z is a monovalent hydrocarbon group, and m is an integer from 1 to 3. The hydrolyzable silane groups, Y of the silane are then activated with moisture to form a durable, tough, high strength, excellent abrasion resistant polymeric material crosslinked through --Si--O--Si--
25 linkages. The balloon structure also has dimension stability during both manufacturing procedures and in use. The high strength crosslinked material allows the balloons to be manufactured having of a relatively thin walled structure.

The present invention further relates to a method of forming a catheter balloon comprising the steps of providing at least one polymeric material at or above its
30 melt temperature, providing at least one organofunctional hydrolyzable silane compound, extruding the polymeric material and the organofunctional hydrolyzable silane

compound into a tubular preform at a temperature wherein the polymeric material and the hydrolyzable silane react, forming the tubular preform into a balloon preform, blowing the balloon preform into a balloon, and exposing the balloon or balloon preform to water. The hydrolyzable groups on the silane are activated by moisture forming a durable polymeric material crosslinked through --Si--O--Si-- linkages..

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a perspective view of a dilatation catheter having attached at its distal end, a catheter balloon of the present invention depicted in its inflated state.

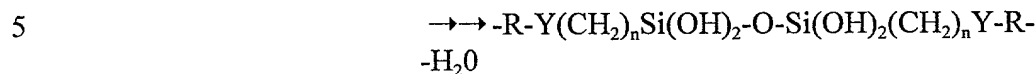
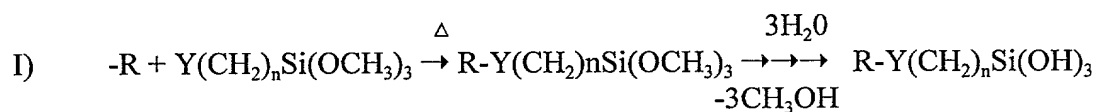
DETAILED DESCRIPTIONS OF THE PREFERRED EMBODIMENTS

The present invention relates to medical balloons that are made of a durable polymeric material crosslinked through --Si--O--Si-- linkages.

The method of preparing the medical balloons of the present invention involves the grafting of hydrolyzable silanes onto a polymer backbone and then moisture curing the resultant polymeric structure. The hydrolyzable groups of the silane are activated upon exposure to moisture forming durable --Si--O--Si-- linkages.

The general reaction scheme representative of the grafting/moisture curing reaction of the present invention generally involves a two-step reaction process in which the first step is the reaction between the hydrolyzable silane compound and the polymer at melt in the absence of moisture, and the second step is the crosslinking reaction in which the hydrolyzable groups of the silane are activated with moisture forming the durable --Si--O--Si-- linkages.

This two step process can be represented by the following general reaction scheme. The first step of the diagram illustrates the reaction between the polymer and the hydrolyzable silane compound. The second and third reactions illustrate hydrolysis and condensation of the polymer to form the --Si--O--Si-- linkages. The latter two reactions occur basically simultaneously and are considered to be the second step.



The silanes useful herein include those having hydrolyzable groups, each
 10 of which is bonded to the silicon atom and that will effectively graft and crosslink to a
 polymer backbone. Hydrolyzable groups include C₁ to C₁₂ alkoxy groups, in particular
 the lower C₁ to C₄ alkoxy groups such as methoxy or ethoxy, C₂ to C₄ acryloxy, up to
 about C₆ (poly)alkoxyalkoxy, phenoxy, oxime, amine, halogen groups including chlorine,
 fluorine and bromine, and so forth. In particular emodiments of the present invention,
 15 hydrolyzable groups including the alkoxy, alkoxyalkoxy and the acryloxy groups are
 used. The hydrolyzable groups, the alkoxy groups for instance, will be activated by
 moisture to form durable structures crosslinked through --Si--O--Si-- linkages.

The organofunctional hydrolyzable silanes useful herein may be broadly
 represented by the following general structure:

20



25 where X is a monovalent non-hydrolyzable organic moiety comprising at least one
 functional group W which is reactive with the polymeric material to which the silane is
 to be grafted with the proviso that at least one Si-C bond is present between Si and W, Y
 is a hydrolyzable group, Z is a monovalent hydrocarbon group, and m is an integer from
 1 to 3. The hydrolyzable silane is useful from about 0.05 wt-% to about 20 wt-% of the
 30 polymer/silane composition.

W may be, but is not limited to, (meth)acrylamido, (meth)acryloxy,
 carboxyl, epoxy, amino, ureido, isocyanato, thiocyanato, mercapto, haloalkyl, styryl,

vinyl, allyl, sulfonyl azide, acid anhydride, or carboxylic acid esters of aromatic alcohols, the alcohols of which have 2 to 15 carbon atoms, and mixtures thereof.

In particular embodiments X is epoxycyclohexyl, glycidoxypropyl, isocyanatopropyl, vinyl or allyl. Other examples of X include, but are not limited to,

- 5 3-acryloxypropyl, 3-methacryloxypropyl, 3-glycidoxypropyl, 2-(3,4-epoxycyclohexyl)ethyl, 3-aminopropyl, N-(2-aminoethyl)-3-aminopropyl, (aminoethylaminomethyl)phenethyl, 3-(1-aminopropoxy)-3,3-dimethyl-1-propenyl, N-phenylaminopropyl, diethylenetriaminopropyl, and 3-ureidopropyl. Organofunctional moieties containing amino functional groups or isocyanato functional groups are particularly versatile in having reactivity or compatibility with a wide range of different polymer types.

In particular embodiments, Y is C₁ to C₄ alkoxy, and m is 2 or 3.

Some examples of specific unsaturated silanes represented by formula II) above that are useful herein include, but are not limited to, those that comprise an

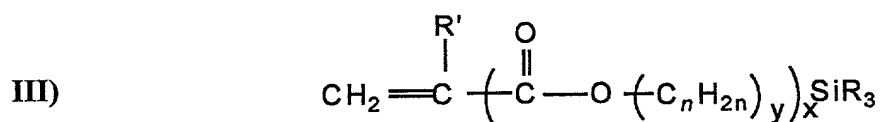
- 15 ethylenically unsaturated hydrocarbyl group, such as a vinyl, allyl, isopropenyl, butenyl, cyclohexenyl or γ-(meth)acryloxyalkyl group, and a hydrolyzable group, such as, for example, a hydrocarbyloxy, hydrocarbonyloxy, or hydrocarbylamino group. Examples of hydrolyzable groups include methoxy, ethoxy, formyloxy, acetoxy, propionyloxy, and alkyl or arylamino groups.

- 20 Preferred silanes of this category are the unsaturated alkoxy silanes which can be grafted onto the polymer.

Some of these unsaturated silanes and their method of preparation are more fully described in US 5312861 and US 5266627, both of which are incorporated by reference herein in their entirety. Specific examples of these silanes for use herein are

- 25 vinyl trimethoxy silane, vinyl triethoxy silane, γ-(meth)acryloxy propyl trimethoxy silane, allyltrimethoxysilane, and so forth.

A particular class of hydrolyzable silanes useful herein include those represented by the following general formula:



where R' is a hydrogen atom or lower C₁ to C₄ alkyl, particularly methyl; x and y are 0 or 1 with the proviso that when x is 1, y is 1; n is an integer from 1 to 12 inclusive, preferably 1 to 4, and each R independently is a hydrolyzable organic group such as an alkoxy group having from 1 to 12 carbon atoms (e.g. methoxy, ethoxy, butoxy), aryloxy group (e.g. phenoxy), araloxy group (e.g. benzyloxy), aliphatic acyloxy group having from 1 to 12 carbon atoms (e.g. formyloxy, acetyloxy, propanoyloxy), amino or substituted amino groups (alkylamino, arylamino), or a lower alkyl group having 1 to 6 carbon atoms inclusive, with the proviso that not more than one of the three R groups is an alkyl.

Other silanes useful herein include but are not limited to, 3-acryloxypropyltrimethoxysilane, 3-methacryloxypropyltrimethoxysilane, 3-methacryloxypropyltris(methoxyethoxy)silane, 3-glycidoxypropyltrimethoxysilane, (3-glycidoxypropyl)methyldiethoxysilane, 3-aminopropyltriethoxysilane, 2-(3,4-epoxycyclohexyl)ethyltrimethoxysilane, (3-aminopropyl)methyldiethoxysilane, N-(2-aminoethyl)-3-aminopropyltrimethoxysilane, N-(2-aminoethyl)-3-aminopropylmethyldimethoxysilane, (aminoethylaminomethyl)phenethyltrimethoxysilane, 3-(1-aminopropoxy)-3,3-dimethyl-1-propenyltrimethoxysilane, N-phenylaminopropyltrimethoxysilane, (3-trimethoxysilylpropyl)diethylenetriamine, ureidopropyltriethoxysilane, 3-isocyanatopropyltriethoxysilane, 3-thiocyanatopropyltriethoxysilane, 3-mercaptopropyltriethoxysilane, 3-(N-styrylmethyl-2-aminoethylamino)propyltrimethoxysilane hydrochloride, phenyltriethoxysilane, phenethyltrimethoxysilane, (p-chloromethyl)phenyltrimethoxysilane, (chloromethyl)phenylethyltrimethoxysilane, and so forth.

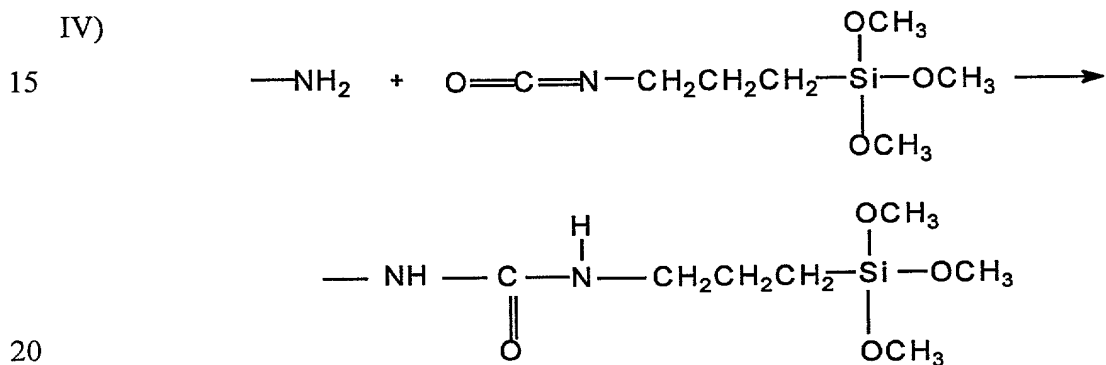
Suitable polymers include, but are not limited to, polyolefins such as polyethylene and polypropylene, and substantially linear ethylene and propylene α -olefins; acrylic polymers; copolymers of olefins and acrylic acid ester copolymers thermoplastic or elastomeric polyurethanes; thermoplastic or elastomeric polyesters; polyamides; polysulfones; polyvinyls; and so forth.

The incorporation of silanes into polyamides, as well as other polymers including polyolefins, is discussed in US 4637640 and in US 5055249 both of which are incorporated by reference herein in their entirety.

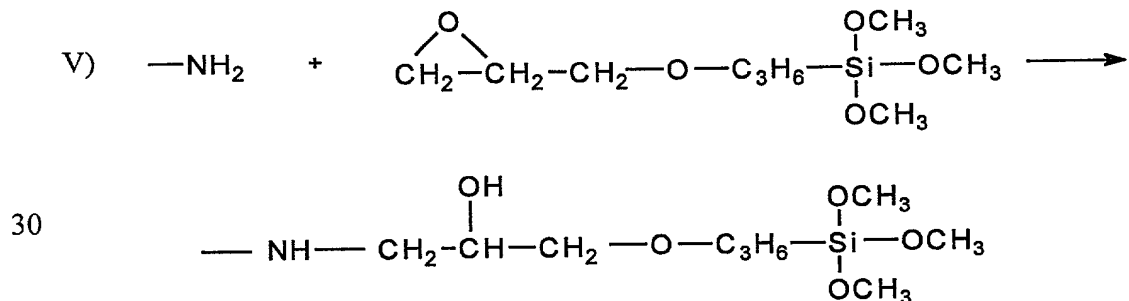
Some specific embodiments of the present invention are represented by the following reaction mechanisms. In some specific embodiments, an amino functional polymer, is reacted with an isocyanate functional hydrolyzable silane.

Poly(meth)acrylate polymers having pendant hydroxy groups thereon can be also be reacted with isocyanato functional alkoxy silanes. These types of reactions have been found to have particular utility herein.

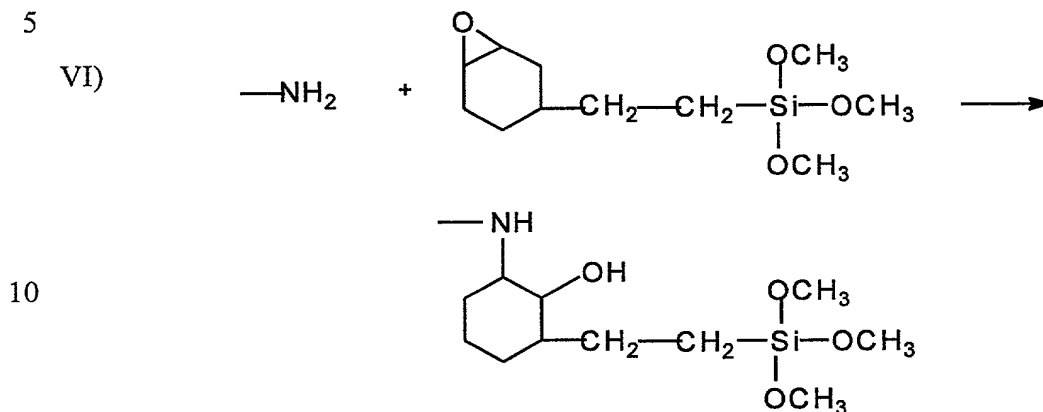
For instance, an example of a reaction between the isocyanate functional silane compound, isocyanatopropyltriethoxy silane, and an amine containing polymer may be represented by the following general reaction scheme:



An example of a reaction in which a silane compound having epoxy functionality is reacted with a polymer having amine functionality may be represented by the following general reaction scheme:

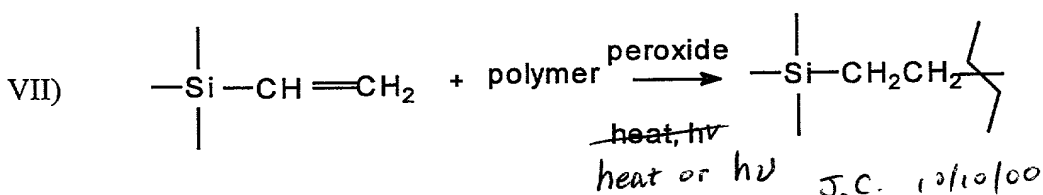


Another example of a reaction between a different epoxy functional silane and a polymeric amine containing compound may be represented by the following general reaction scheme:



A specific method of grafting an unsaturated hydrolyzable silane onto the backbone of a polymer is by a free radical mechanism in which a free radical initiator, such as an organic peroxide, is used.

The following reaction mechanism is representative of an unsaturated silane, i.e. in this case a vinyl containing silane, reacted onto a polymer backbone by a free radical mechanism using a peroxide as the free radical initiator.



The second part of the reaction process is a moisture curing step in which the hydrolyzable alkoxy groups of the silane in the presence of moisture, react to form polymers which are crosslinked by the presence of --Si--O--Si-- linkages. These crosslinked polymers provide structures which are more durable, abrasion resistant, tear resistant and dimensionally stable during sterilization than non-crosslinked polymeric materials.

The resultant crosslinked material finds particular utility in medical devices, especially in angioplasty catheter balloons where the durability and toughness are especially important.

In the preparation of the medical devices of the present invention, a
5 tubular preform is first prepared by mild blending and extruding the amine containing polymeric material and the functional silane compound together at a temperature of greater than the melting temperature of the polymer(s) in the absence of moisture. The tubular preform may be prepared using any extrusion techniques known in the art.

The tubular preform may then be fed into a balloon mold. The balloon is
10 then exposed to moisture in some form in order to produce the crosslinked balloon structure of the present invention. This exposure to moisture may occur by actually forming the balloon in a water bath at temperatures and pressures typically used for balloon formation, or it may occur after balloon formation, for instance by placing the already formed balloon in a water bath with or without pressure.

15 Balloons are typically formed using a blow molding technique. However, balloon formation may be carried out in any conventional manner with conventional extrusion and blowing techniques, but basically there are three major steps in the process which include extruding the tubular preform, blow molding the balloon and annealing the balloon. The preform may be axially stretched and/or biaxially oriented before it is
20 blown. General techniques for balloon formation are discussed in U.S. Patent No. 4,490,421 to Levy and in U.S. Patent no. 5,348,538 issued September 20, 1994 to Wang et al. Fig. 1 is a perspective view of dilatation catheter shown in its inflated state having attached at its distal end a catheter balloon shown generally at 10. Catheter balloon 14 is formed of the crosslinked polymeric material of the present invention and is conventional
25 in its structure having a body portion 12, cone portions 14 and waist portion 16. One of skill in the art will recognize that the moisture cured polymeric materials of the present invention may be utilized in any catheter balloon configuration capable of being formed from a polymeric material, and that numerous modifications can be made to these structures without departing from the spirit and scope of the present invention.

30 The exposure of the alkoxy groups of the silane to moisture results in the crosslinking reaction. After forming, the balloon may be kept in the hot water bath under

pressure and tension at conventional molding temperatures such as in the range of about 65° C to about 145° C for a predetermined time to ensure completion of the crosslinking process. Any remaining uncrosslinked functional groups, however, will undergo crosslinking over time.

5 The resultant process for manufacturing the improved balloons of the present invention is thus very simple without the introduction of extra steps into the process of preparing the tubular preform.

 As compared to some prior art methods, there is no requirement for radiation or e-beams using the method of the present invention. One disadvantage
10 known to using e-beams is that it is difficult to get a full cure without any chain scission occurring. Further, the e-beam process is not economical.

 The embodiments described herein are in no way intended to limit the present invention and one of skill in the art will recognize that modifications can be made without departing from the spirit and scope of the present invention.

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CLAIMS:

1. A medical device formed of moisture curable materials, comprising:
a dilatation balloon formed from a crosslinked polymeric material, the
crosslinked polymeric material comprising the reaction product of:

- 5 I) at least one polymer; and
II) at least one hydrolyzable silane having the following general
structure:



15 where X is a monovalent non-hydrolyzable organic moiety comprising at least
one functional group W which is reactive with said polymer with the proviso that
an Si-C bond is present between Si and W, Y is a hydrolyzable group, Z is a
monovalent hydrocarbon group, and m is an integer from 1 to 3;
said reaction product having been further reacted with moisture to produce a
polymeric material crosslinked through --Si--O--Si-- linkages.

- 20 2. The device of Claim 1 wherein Y is an alkoxy group having from 1 to 4 carbon
atoms.
3. The device of Claim 1 wherein W is selected from (meth)acrylamido,
(meth)acryloxy, carboxyl, epoxy, amino, ureido, isocyanato, thiocyanato,
mercapto, styryl, vinyl, allyl, haloalkyl, acid anhydride, sulfonyl azide, carboxylic
25 acid esters of aromatic alcohols, and mixtures thereof.
4. The device of Claim 1 wherein X is selected from epoxycyclohexyl,
glycidoxypropyl, isocyanatopropyl, vinyl, and allyl.
- 30 5. The device of Claim 1 wherein said at least one hydrolyzable silane comprises an
organofunctional group capable of readily reacting with a primary or secondary

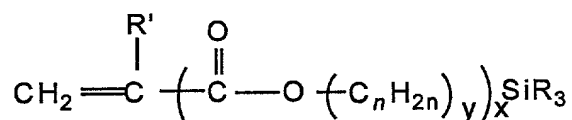
amine and said at least one polymer is an amino functional polymer.

6. The catheter device of Claim 1 wherein said hydrolyzable silane is selected from isocyanatoalkylalkoxysilanes, glycidoxyalkylalkoxysilanes and epoxycyclohexylalkylalkoxysilanes.

5

7. The device of Claim 6 wherein said hydrolyzable silane is selected from isocyanatopropyltriethoxysilane, glycidoxypropyltrimethoxysilane and 2-(3,4-epoxycyclohexyl)ethyltrimethoxysilane.

- 10 8. The device of Claim 1 wherein at least one hydrolyzable silane has the following general structure:



15

where R' is a hydrogen atom or lower C₁ to C₄ alkyl; x and y are 0 or 1 with the proviso that when x is 1, y is 1; n is an integer from 1 to 12 inclusive, preferably 1 to 4, and each R independently is a hydrolyzable organic group such as an alkoxy group having from 1 to 12 carbon atoms, aryloxy group, aralkoxy group, aliphatic acyloxy group having from 1 to 12 carbon atoms, amino or substituted amino groups, or a lower alkyl group having 1 to 6 carbon atoms inclusive, with the proviso that not more than one of the three R groups is an alkyl.

20

- 25 9. The device of Claim 8 wherein said reaction proceeds by a free radical mechanism.

10. The device of Claim 9 wherein said free radical initiator is an organic peroxide.

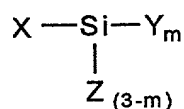
- 30 11. The device of Claim 8 wherein said hydrolyzable silane is selected from vinyltrimethoxysilane, vinyltriethoxysilane, allyltrimethoxysilane,

γ -(meth)acryloxypropyltrimethoxysilane, and mixtures thereof.

12. A balloon catheter comprising a balloon wherein said balloon comprises a moisture cured polymeric material which is crosslinked through --Si--O--Si-- linkages.

13. The balloon catheter of Claim 12 wherein said moisture cured polymeric material is the reaction product of:

- a) at least one polymer; and
b) at least one hydrolyzable silane having the following general structure:



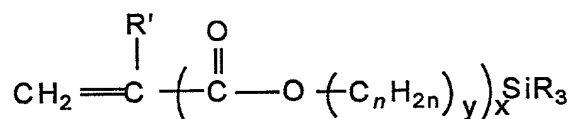
where X is a monovalent non-hydrolyzable organic moiety comprising at least one functional group W which is reactive with said polymer with the proviso that an Si-C bond is present between Si and W, Y is a hydrolyzable group, Z is a monovalent hydrocarbon group, and m is an integer from 1 to 3.

14. The balloon catheter of Claim 13 wherein said at least one hydrolyzable silane has an organofunctional group capable of readily reacting with a primary or secondary amine and said at least one polymer is amino functional.

15. The catheter balloon of Claim 13 wherein Y is an alkoxy of C₁ to C₄.

16. The catheter balloon of Claim 13 wherein W is selected from (meth)acrylamido, (meth)acryloxy, carboxyl, epoxy, amino, ureido, isocyanato, thiocyanato, mercapto, styryl, vinyl, allyl, haloalkyl, acid anhydride, sulfonyl azide, carboxylic acid esters of aromatic alcohols, and mixtures thereof.

17. The catheter balloon of Claim 13 wherein X is selected from epoxycyclohexyl, glycidoxypropyl, isocyanatopropyl, vinyl, and allyl.
18. The catheter balloon of Claim 13 wherein said hydrolyzable silane is selected from isocyanatopropyltriethoxysilane, glycidoxypropyltrimethoxysilane and 2-(3,4-epoxycyclohexyl)ethyltrimethoxysilane.
19. The catheter balloon of Claim 12 wherein said moisture cured polymeric material is the reaction product of:
 - a) at least one polymer; and
 - b) at least one hydrolyzable silane having the following general structure:

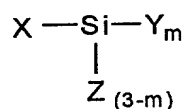


where R' is a hydrogen atom or lower C₁ to C₄ alkyl; x and y are 0 or 1 with the proviso that when x is 1, y is 1; n is an integer from 1 to 12 inclusive, preferably 1 to 4, and each R independently is a hydrolyzable organic group such as an alkoxy group having from 1 to 12 carbon atoms (e.g. methoxy, ethoxy, butoxy), aryloxy group (e.g. phenoxy), araloxy group (e.g. benzyloxy), aliphatic acyloxy group having from 1 to 12 carbon atoms (e.g. formyloxy, acetyloxy, propanoyloxy), amino or substituted amino groups (alkylamino, arylamino), or a lower alkyl group having 1 to 6 carbon atoms inclusive, with the proviso that not more than one of the three R groups is an alkyl.

20. A method of forming a catheter balloon comprising the steps of:
 - a) providing at least one polymeric material at or above its melt temperature;
 - b) providing at least one organofunctional hydrolyzable silane compound;

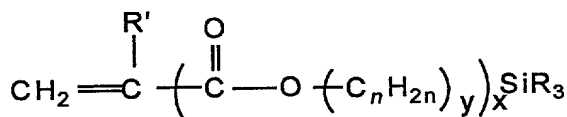
- c) extruding a) and b) into a tubular preform at a temperature wherein a) and b) react;
- d) forming said tubular preform into a balloon preform;
- e) blowing said balloon preform into a balloon; and
- 5 f) exposing said balloon or balloon preform to water;
- wherein said a) and b) react to form a polymeric material having hydrolyzable groups on said silane wherein said hydrolyzable groups crosslink upon exposure to water and form --Si--O--Si-- linkages..

- 10 21. The method of Claim 20 wherein said at least one organofunctional hydrolyzable silane has the following general structure:



15 where X is a monovalent non-hydrolyzable organic moiety comprising at least one functional group W which is reactive with said polymeric material with the proviso that an Si-C bond is present between Si and W; Y is a hydrolyzable group, Z is a monovalent hydrocarbon group, and m is an integer from 1 to 3.

- 20 22. The method of Claim 20 wherein said at least one hydrolyzable silane has the following general structure:



25 where R' is a hydrogen atom or lower C₁ to C₄ alkyl; x and y are 0 or 1 with the proviso that when x is 1, y is 1; n is an integer from 1 to 12 inclusive, preferably 1 to 4, and each R independently is a hydrolyzable organic group such as an

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alkoxy group having from 1 to 12 carbon atoms, aryloxy group, araloxy group, aliphatic acyloxy group having from 1 to 12 carbon atoms, amino or substituted amino groups, or a lower alkyl group having 1 to 6 carbon atoms inclusive, with the proviso that not more than one of the three R groups is an alkyl.

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23. The method of Claim 22 wherein said hydrolyzable silane is selected from vinyltrimethoxysilane, vinyltriethoxysilane, allytrimethoxysilane, and γ -(meth)acryloxypropyltrimethoxysilane.

10 24. The method of Claim 21 wherein W is selected from (meth)acrylamido, (meth)acryloxy, carboxyl, epoxy, amino, ureido, isocyanato, thiocyanato, mercapto, styryl, vinyl, allyl, haloalkyl, acid anhydride, sulfonyl azide, carboxylic acid esters of aromatic alcohols, and mixtures thereof.

15 25. The method of Claim 21 wherein X is selected from epoxycyclohexyl, glycidoxypropyl, isocyanatopropyl, vinyl, and allyl.

26. The method of Claim 21 wherein Y is alkoxy of C₁ to C₄.

20 27. The method of Claim 21 wherein said hydrolyzable silane is selected from isocyanatopropyltriethoxysilane, glycidoxypropyltrimethoxysilane and 2-(3,4-epoxycyclohexyl)ethyltrimethoxysilane.

28. The method of Claim 20 wherein said polymeric material is amino functional.

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29. The method of Claim 20 wherein said exposure to water is accomplished in a water bath.

30 30. The method of Claim 20 wherein in during said blowing step, said balloon is further axially stretched.

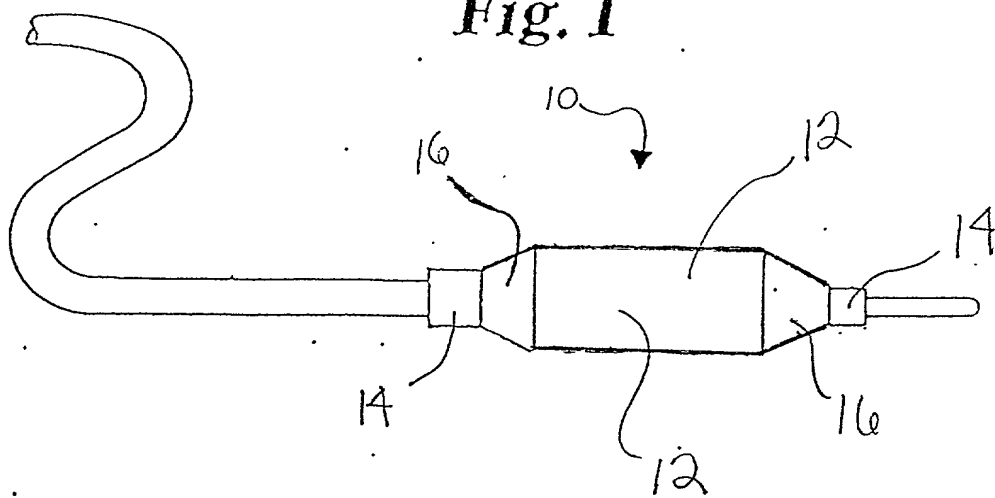
MOISTURE CURABLE BALLOON MATERIALS

ABSTRACT OF THE INVENTION

The present invention relates to a catheter device having a dilatation
5 balloon formed from a polymeric material crosslinked by moisture through --Si--O--Si--
linkages, and to a method of making the same. The polymeric material is formed by
reacting at least one organofunctional hydrolyzable silane with at least one polymer.
The crosslinked polymeric structure is ideal for forming more resilient and durable
catheter balloons. In particular, the catheter balloons have excellent abrasion resistance.

10

Fig. 1



DECLARATION

As a below-named inventor, I(we) hereby declare that:

TYPE OF DECLARATION

This declaration is of the following type:

- ☒ original
- ☐ design
- ☐ supplemental
- ☐ national stage of PCT
- ☐ divisional
- ☐ continuation
- ☐ continuation-in-part (CIP)

INVENTORSHIP DECLARATION

My residence, post office address, and citizenship are as stated below next to my name;

I verily believe I am the original, first and sole inventor (*if only one name is listed below*) or an original, first and joint inventor (*if plural names are listed below*) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

MOISTURE CURABLE BALLOON MATERIALS

the specification of which:

- a) ☒ is being filed concurrently herewith
- b) ☐ was filed on _____ and assigned Serial No. _____
- c) ☐ was filed as PCT International Application No. _____ filed on _____ and amended under PCT Article 19 on _____.

ACKNOWLEDGMENT OF REVIEW OF PAPERS AND DUTY OF CANDOR

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations §1.56 including information occurring between the filing date of any prior application of which the present application is a continuation-in-part.

- ☐ In compliance with this duty there is attached an Information Disclosure Statement.
37 CFR 1.97.

PRIORITY CLAIM

I hereby claim foreign priority benefits under Title 35, United States Code, §119(a)-(d), of any foreign application(s) for patent or inventor's certificate or of any PCT international applications(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application for patent or inventor's certificate or any PCT international applications(s) designating at least one country other than the United States of America filed by me having the same subject matter having a filing date before that of the application on which priority is claimed.

- a) ☒ no such applications have been filed.
b) ☐ such applications have been filed as follows:

COUNTRY	APPLICATION NUMBER	DATE OF FILING (day, month, year)	PRIORITY CLAIMED UNDER 37 USC 119
			<input type="checkbox"/> YES <input type="checkbox"/> NO
			<input type="checkbox"/> YES <input type="checkbox"/> NO
			<input type="checkbox"/> YES <input type="checkbox"/> NO
			<input type="checkbox"/> YES <input type="checkbox"/> NO

I hereby claim the benefit under Title 35 United States Code, §119(e) of any United States provisional application identified below.

- a) ☒ no such applications have been filed.
b) ☐ such applications have been filed as follows:

U.S. APPLICATIONS	
SERIAL NUMBER	U.S. FILING DATE
1.	
2.	

CLAIM FOR BENEFIT OF EARLIER U.S./PCT APPLICATIONS(S) UNDER 35 U.S.C. §120

I hereby claim the benefit under Title 35, United States Code, §120 of any United States applications(s) or PCT international applications(s) designating the United States of America that is/are listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in that/those prior applications(s) in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56 which occurred between the filing date of the prior applications(s) and the national or PCT international filing date of this application.

- a) ☒ no such applications have been filed.
b) ☐ such applications have been filed as follows:

U.S. APPLICATIONS	
SERIAL NUMBER	U.S. FILING DATE
1.	
2.	
PCT APPLICATIONS DESIGNATING THE U.S.	
PCT APPLICATION NO.	PCT FILING DATE
3.	

I hereby declare that all statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Telephone calls and correspondence should be directed to: **Lisa L. Ryan-Lindquist, at Customer No. 490, Telephone: (952) 563-3000, Facsimile: (952) 563-3001.**

First Inventor

Full name

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Inventor's signature



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(If different than above)

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Full name

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Date

Citizenship

Post office Address

Residence

(If different than above)

UTILITY/DESIGN PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s):	Chen
Title:	MOISTURE CURABLE BALLOON MATERIALS
Filed:	<input checked="" type="checkbox"/> concurrently herewith
	<input type="checkbox"/> on _____ and assigned Serial No. _____

Commissioner for Patents
Washington, DC 20231

Docket No: S63.2-9178

POWER OF ATTORNEY FROM ASSIGNEE

As assignee of record of the entire interest of the above identified patent application,
SCIMED LIFE SYSTEMS, INC. hereby appoint all practitioners of **Customer No. 490** to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith. I hereby authorize them to act and rely on instructions from, and to communicate directly with, the firm or person which sent this case to Vidas, Arrett & Steinkraus, P.A., unless or until I instruct Vidas, Arrett & Steinkraus P.A., in writing to the contrary.

Address all correspondence to at Customer Number 490.

Dated this 10th day of October, 2000.

(Company Name)

SCIMED LIFE SYSTEMS, INC.

(Signature)

By:

(typed name)

Luke Dohmen

(title)

Its:

Senior Patent Attorney

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s):	Chen
Title:	MOISTURE CURABLE BALLOON MATERIALS
Filed:	<input checked="" type="checkbox"/> concurrently herewith <input type="checkbox"/> on _____ and assigned Serial No. _____

Box Patent Application
Commissioner for Patents
Washington, D.C. 20231

Docket No.: S63.2-9178

CORRESPONDENCE ADDRESS OF LAW FIRM

Vidas, Arrett & Steinkraus P.A. would like to make the following correspondence address of record. Please send all correspondence for this application to the address as follows:



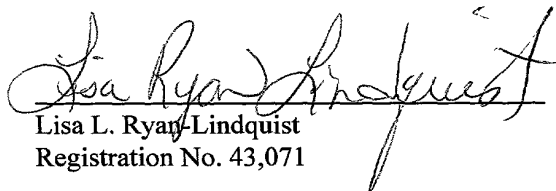
00490

PATENT TRADEMARK OFFICE

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

By:


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